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PATENT COOPERATION TREATY

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NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

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Date of mailing (day/month/year) 21 November 2000 (21.11.00)	
International application No. PCT/US00/06164	Applicant's or agent's file reference 1365 WO
International filing date (day/month/year) 09 March 2000 (09.03.00)	Priority date (day/month/year) 12 March 1999 (12.03.99)
Applicant FINI, Massimo et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
22 September 2000 (22.09.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 07 FEB 2000

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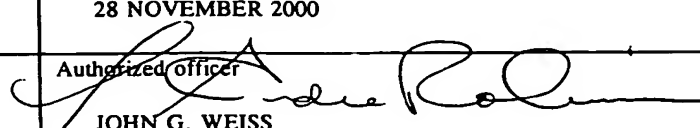
15

Applicant's or agent's file reference 1365 WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/06164	International filing date (day/month/year) 09 MARCH 2000	Priority date (day/month/year) 12 MARCH 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A62B 18/02, 08 and US Cl.: 128/206.24, 206.26		
Applicant MALLINCKRODT INC.		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 3 sheets.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22 SEPTEMBER 2000	Date of completion of this report 28 NOVEMBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  JOHN G. WEISS
Facsimile No. (703) 305-3230	Telephone No. (703) 306-5444

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/06164

I. Basis of the report**1. With regard to the elements of the international application:***☒ the international application as originally filed☒ the description:

pages 1-4 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the claims:

pages 5 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the drawings:

pages 1 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the sequence listing part of the description:

pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/06164

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)

Claims 1-5 YESClaims NONE NO

Inventive Step (IS)

Claims 1-5 YESClaims NONE NO

Industrial Applicability (IA)

Claims 1-5 YESClaims NONE NO**2. citations and explanations (Rule 70.7)**

Claims 1-5 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a face or nose mask having a mask body with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for applying to the face of a patient, the sealing element having at least a first chamber and at least a second chamber which can be connected separately to a source of pressurized air.

----- NEW CITATIONS -----

NONE

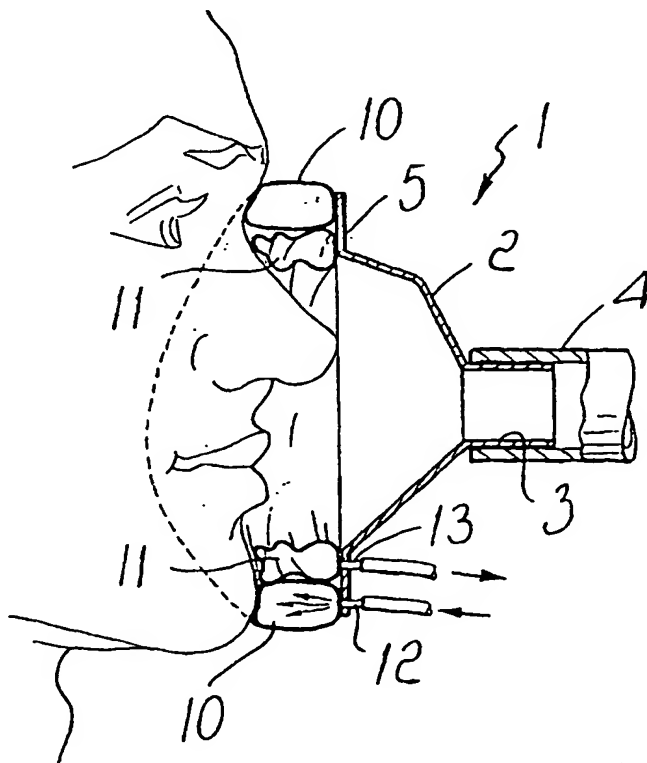
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A62B 18/02, 18/08	A1	(11) International Publication Number: WO 00/53265 (43) International Publication Date: 14 September 2000 (14.09.00)
<p>(21) International Application Number: PCT/US00/06164</p> <p>(22) International Filing Date: 9 March 2000 (09.03.00)</p> <p>(30) Priority Data: MI99A000521 12 March 1999 (12.03.99) IT</p> <p>(71) Applicant (for all designated States except US): MALLINCK-RODT INC. [US/US]; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): FINI, Massimo [IT/IT]; Via P. Picasso, 31, I-41037 Mirandola (IT). BERGAM-ASCHI, Paolo [IT/IT]; Via Fratelli Cervi, 12, I-41033 Concordia (IT). NAVA, Stefano [IT/IT]; Pzza Duomo, 7/A, I-26013 Crema (IT).</p> <p>(74) Agents: LIMPUS, Lawrence, L. et al.; 675 McDonnell Boulevard, P.O. Box 5840, St. Louis, MO 63134 (US).</p>	<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</p>	

(54) Title: FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF PATIENTS IN GENERAL

(57) Abstract

This invention is a face or nose mask (1) comprising a mask body (2) with an inlet (3). The mask body (2) having a sealing element with a first chamber (10), and a second chamber (11) which can be connected by connectors (12, 13) to a source of pressurized air.



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FACE OR NOSE MASK FOR NON-INVASIVE VENTILATION OF PATIENTS IN GENERAL

The present invention relates to a face or nose mask for non-invasive ventilation of patients in general.

5 It is known that the main problem in long-term ventilation performed by means of a mask is the tolerability of the mask by the patient.

One of the most unpleasant and harmful effects arises from the compression of the skin that is produced by the sealing element provided in the perimetric region of the mask, which is pressed against the user's face;
10 this effect is particularly damaging at the upper nasal region.

The pressure applied by the mask in fact reduces blood flow in the affected part of the skin and in the long term causes pain and sores may form in the region.

In order to try to at least partially solve this problem, masks have already
15 been provided in which the sealing element is formed in practice by an air-filled chamber or air cushion which, in order to reduce the period of contact with the skin, is in practice deflated at least at the upper part of the nasal septum during expiration, a step in which there is no need to provide a seal since the patient is expelling air. The chamber is then instantly reinflated
20 during inspiration, thus forming a seal again and in practice reducing the time of contact between the skin and the inflatable chamber.

Also this solution has not proved to be particularly effective, since the inflation and deflation rate is closely dependent on the ratio between the expiration phase and the inspiration phase and because a relatively high
25 residual pressure always remains and is applied by the mask to the skin.

The aim of the present invention is to eliminate the above-noted drawbacks, by providing a face or nose mask for non-invasive ventilation of patients in general which allows to reduce the time for which the pressure produced by the sealing element of the mask is applied, so that the above-
30 mentioned problems do not occur since blood flow in the affected skin

portion is possible at all times.

Within the scope of this aim, a particular object of the present invention is to provide a face or nose mask in which the perfect seal of the mask with respect to the outside is ensured at all times but the region where pressure is applied to the skin changes continuously.

Another object of the present invention is to provide a mask in which the system for inflating the sealing element is independent of the ventilation system, consequently allowing a wide range of adjustment for the pressure values used.

Another object of the present invention is to provide a mask which, by way of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

Another object of the present invention is to provide a face or nose mask for non-invasive ventilation of patients in general which can be easily obtained starting from commonly commercially available elements and materials and is also competitive from a purely economical point of view.

This aim, these objects and others which will become apparent hereinafter are achieved by a face or nose mask for non-invasive ventilation of patients in general, according to the invention, which comprises a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, characterized in that said sealing element comprises at least one first chamber and at least one second chamber which can be connected separately to a source of pressurized air.

Further characteristics and advantages of the present invention will become apparent from the following detailed description of a preferred but not exclusive embodiment of a face or nose mask for non-invasive ventilation of patients in general, illustrated only by way of non-limitative example in the accompanying drawings, wherein:

Figure 1 is a partially sectional schematic view of the mask according to

the invention with the seal provided by one chamber; and

Figure 2 is a view of the mask with the seal produced by the other chamber.

With reference to the above figures, the face or nose mask for non-invasive ventilation of patients in general, according to the invention, generally designated by the reference numeral 1, comprises a mask body 2 which has the conventional configuration of a face or nose mask and is provided with an inlet 3 for connection, by means of a hose 4, to a ventilation apparatus.

In the perimetric region, the mask has a flange 5 at which the sealing element for application to the face of the patient is provided.

The particularity of the invention is constituted by the fact that the sealing element is provided by at least one first chamber 10 and by at least one second chamber 11 which are advantageously arranged side by side, the first chamber being arranged outside with respect to the second chamber.

The chambers have separate connections to a source of pressurized air, and in particular there is provided a first connector 12 for the first chamber 10 and a second connector 13 for the second chamber 11; such connectors are connected to an inflation device which is constituted for example by extremely compact micropumps which can be actuated sequentially so as to release the pressure in one chamber and inflate the other chamber, thus ensuring the seal.

The inflation and deflation rate can be adjusted in any manner, since it is independent of the ventilator of the ventilation system.

In practice it is possible to alternate inflation and deflation with a period of a few seconds, consequently having the advantage that the skin is affected in the same region for a period which is substantially halved, but most of all with the advantage that in practice blood flow is never interrupted or hindered, thus preventing the occurrence of pain and dangerous sores.

In practice, the system adopted consists in removing pressure from one chamber and simultaneously restoring pressure in the other chamber, so that the seal is ensured at all times but the region where pressure is applied to the skin changes.

5 Advantageously, the chambers have a closed perimeter, but from the conceptual point of view there is no difference if the chambers 10, 11 affect only portions of the face and in any case the regions that are more severely affected by pain or sores, depending on the pressure applied in order to provide the seal.

10 From the above description it is thus evident that the invention achieves the intended aim and objects, and in particular the fact is stressed that a face mask is provided which has an inflatable sealing element which is entirely autonomous and independent of the ventilator used for ventilation, thus allowing to adjust the pressure inside the individual chambers independently
15 of each other and to provide alternating deflation and inflation of the chambers at a rate which can be adjusted at will in view of the fact that the chambers are separately connected to a source of pressurized air, for example constituted by micropumps.

20 The invention thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

 All the details may also be replaced with other technically equivalent elements.

 In practice, the materials employed, as well as the contingent shapes and the dimensions, may be any according to requirements.

CLAIMS

1. A face or nose mask for non-invasive ventilation of patients in general, comprising a mask body provided with an inlet for connection to a ventilation apparatus and perimetrically provided with a sealing element for application to the face of a patient, characterized in that said sealing element
5 comprises at least one first chamber and at least one second chamber which can be connected separately to a source of pressurized air.

2. The mask according to claim 1, characterized in that said first and second chambers have a closed perimeter.

10 3. The mask according to the preceding claims, characterized in that said first and second chambers lie side by side, one inside the other.

4. The mask according to one or more of the preceding claims, characterized in that said first and second chambers are alternately connected to said pressurized air source.

15 5. The mask according to one or more of the preceding claims, characterized in that said pressurized air source is constituted by micropumps, each of which is connected to the corresponding chamber.

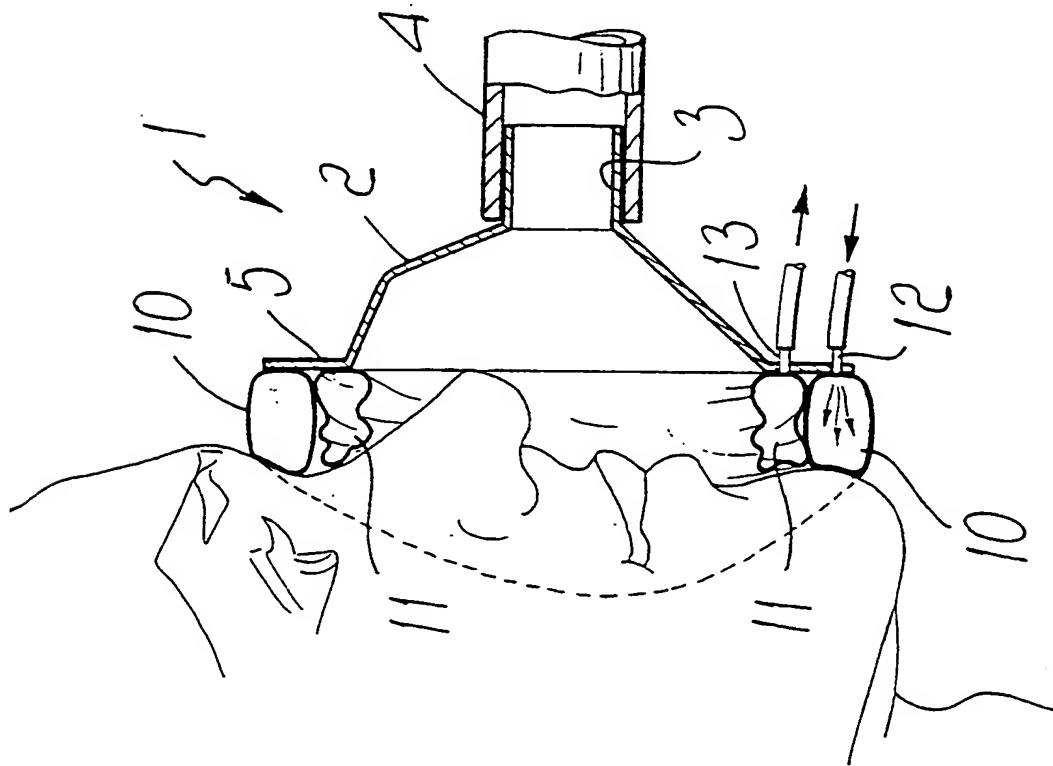


Fig. 1

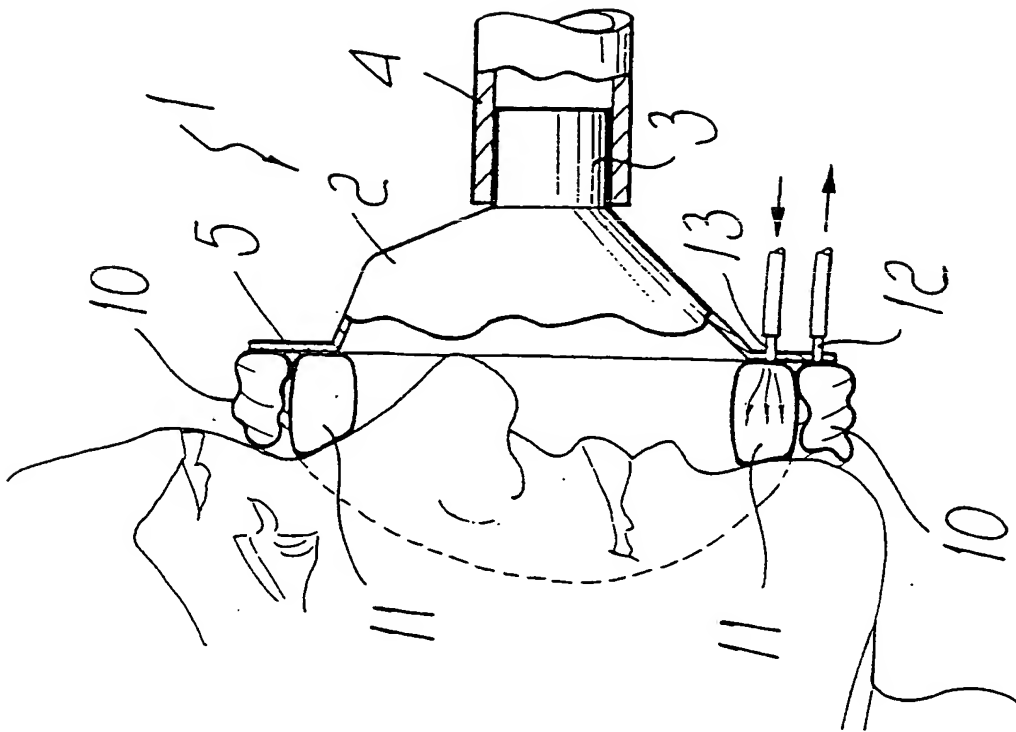


Fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/06164**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :A62B 18/02, 08

US CL :128/206.24, 206.26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/206.24, 206.26

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WEST 2.0

Search Terms: chamber and sealing

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,660,174 A (JACOBELLI) 26 August 1997, entire document.	1-5
A	US 4,971,051 A (TOFFOLON) 20 November 1990, entire document.	1-5
A	US 4,799,477 A (LEWIS) 24 January 1989, entire document.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

13 JUNE 2000

Date of mailing of the international search report

20 JUL 2000

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